Response To "Are Guidelines Tor Standardized Outcome Reporting In Bariatric Surgery Responsible For Missing The Big Picture In Bariatric Surgery Related Major Complications?

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Response to: ''Are Guidelines for Standardized Outcome Reporting in Bariatric Surgery Responsible for Missing the Big Picture in Bariatric Surgery Related Major Complications?''

Reply:

We thank Fysekidis et al[1] for their important comments on the general concept of reporting bariatric outcomes. Ideal complication reporting in surgery has been a matter of debate for a long time. In bariatric surgery, it is even more complex as the main outcome of obesity treatment is not only weight loss but a combination of weight loss, reduction in comorbidity and mortality, increase of quality of life, and complications. The BAROS score intended to implement these factors in a scoring system that never really gained wide acceptance.

Fysekidis et al[1] challenge in their letter to the editor our interpretations of the 3-year results of the ''Swiss Multicentre Bypass or Sleeve Study'' (SM-BOSS) on BAROS score regarding equal effectiveness in terms of weight loss and complication rate.[2]

We would like to respond to the specific questions/remarks as follows:

(i) Dilution of number of complications: It is widely accepted in the surgical literature to differ between early (<30 days) and late morbidity (>30 days). The current article covers an interim analysis of the SM-BOSS trial. Thus, it is too early to draw final conclusions on which of the 2 operations, bypass or sleeve, is safer. A combination of early and late morbidity will have to be analyzed when all patients have reached the 5-year follow up.

(ii) Correct sample size for PRT: It is much easier to have a large enough sample size for comparison of continuous variables such as weight loss. To compare the prevalence of complications between 2 surgical treatment arms, a large number of patients in each group would be necessary to gain enough power. This is especially true for bariatric surgery which in general has a very low complication rate. The acceptance rate for patients to be randomly assigned to 2 surgical procedures that are anatomically quite different was in our trial approximately 5%. Swiss patients often have a firm idea on the type of operation they prefer and it was challenging to convince them to accept randomization. SM-BOSS is the largest PRT up to today comparing early and mid-term results of sleeve and bypass but there are larger studies recruiting presently, for example, the ''Bypass Equipoise Sleeve Trial'' in Sweden (BEST, https://clinicaltrials.gov/ct2/show/NCT02767505) aiming to recruit 4000 patients. BEST should be better suited to answer the issue of safety of the 2 procedures.

(iii) Early morbidity: In the analysis of the 1 year results,[3] we presented the data in Table 2 first by listing major and minor complications (major = need for intervention/operation and minor = medical treatment only) and second by quantifying them with the Clavien-Dindo score.[4] This scoring system aims to allow comparison between groups based on the therapy necessary to treat the complication. It also allows comparison between different trials. Complications grade III and higher are interpreted as major as they require a surgical, endoscopic, or radiological intervention with or without general anaesthesia. However, we were unable to find a significant difference in complication rates of grad III or higher between sleeve (n = 1) and bypass (n = 5).

(iv) Late morbidity: We agree that we did not quantify the late morbidity similar to the Clavien-Dindo score in the 3-year article.[5] Till now, no validated score for late complications exists. However, the numbers mentioned by Fysekidis et al[6] for ''reoperations for major complications'' are incorrect. In the sleeve group, 2 patients had to be converted to bypass because of severe reflux, and another 2 were reoperated for insufficient weight loss as compared with 6 patients in the bypass group that were reoperated until 3 years postoperation (internal hernia, bowel obstruction, and insufficient weight loss). Thus, total ''major'' complications needing reoperation between primary operation until 3 years postoperation, that is, early and late morbidity together, were 5 in the sleeve and 11 in the bypass group (4.8% vs 10%, $P = 0.13$). Furthermore, the long-term issue of gastroesophageal reflux after sleeve has to be taken into account when discussing the safety of the 2 procedures. In a recent article by Genco et al,[6] 17% of 110 asymptomatic patients showed signs of Barrett's esophagus after a mean of 58 months postsleeve. In other words, although the long-term side effects of the bypass procedures are well documented, as the first bypass procedures were performed over 50 years ago, we still do not know all possible side effects of sleeve gastrectomy yet.

In conclusion: we agree with Fysekidis et al[1] that early and long-term morbidity have to be taken into account when judging the safety of a procedure. So far, the 1- and 3-year analysis of the SM-BOSS trial show, that both sleeve and bypass seem equally effective in terms of weight loss and remission of comorbidity except for GERD, dyslipidemia and possibly type 2 diabetes (SM-BOSS is underpowered for that particular secondary endpoint). Further, there may be a trend for a superior safety profile of the sleeve gastrectomy ($P = 0.13$, underpowered for this endpoint). However, please note that final conclusions can only be drawn at 5 years' follow up and longer as there seems to be better weight loss and a higher rate of type 2 diabetes remission after bypass with longer follow up.[7,8] Future SM-BOSS analyses and results from other trials will hopefully enable us to allocate morbidly obese patients to the optimal bariatric procedure and thus improve the individual result.

In the meantime, it is reassuring to know that sleeve gastrectomy is a potent and safe bariatric operation and can be offered to selected patients.

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Letter to the Editor: Stopping the Bleeding Is Not Enough

To the Editor:

As representatives of the American College of Surgeons Committee on Trauma (ACS COT), we gratefully provide comment and context to the Surgical Perspective article published in your January 2017 issue.[1] Drs Masiakos and Warshaw emphasize the importance of injury prevention, and we at the ACS COT could not agree more strongly. In response and for perspective clarity, we wish to emphasize that the ACS COT's approach to firearm injury is and has been comprehensive. ACS COT strategy is built on a trauma system (public health) model aimed at preventing injuries from occurring (thus the description of our firearm injury prevention program detailed below); achieving rapid and effective treatment at the scene of injury (thus our Stop the Bleed Program and support for EMS); rapid, definitive, quality treatment of the injured patient [trauma center verification review and consultation (VRC), Trauma Quality Improvement Program (TQIP), Performance Improvement and Patient Safety (PIPS), etc]; and rehabilitation and reintegration (VRC).

For at least 3 decades, the ACS COT has advocated for prevention of firearm injury and death, and also for treatment. Many of these efforts have stalled because of a lack of consensus among surgeons (and the public) regarding how best to proceed. Most recently, we initiated a concerted and dedicated effort to achieve consensus around how best to eliminate unnecessary death and suffering related to firearm injury.

We began by publishing a description of our view on a public health approach to firearm injury prevention and on how consensus might be reached to address this significant public health challenge in an article entitled "*Firearm injury prevention: A consensus approach to reducing preventable deaths*."[2]

Next, to clearly understand the opinions of ACS COT members regarding the importance of firearm injury prevention and possible advocacy initiatives, we conducted a member survey to help guide injury prevention and policy efforts, and we hosted a town hall of our members.[3] Our survey response rate was 93%; 88% of respondents believe that the American College of Surgeons should give the highest or a high level of priority to reducing gun injuries; 95% agree that healthcare professionals should be allowed to counsel patients about how to prevent gun-related injury; 96% agree that federal funds should be used to fund research on epidemiology and prevention of firearm-related injuries. We also asked COT members to indicate their support for American College of Surgeons' advocacy initiatives regarding 15 potential policy initiatives.[4] A brief summary of some of the results of this survey is listed below:

- Support steps for Congress to appropriate federal funds to conduct research to better understand and to prevent firearm injuries and death (92% support or strongly support);
- Monitor and advocate for legislation that enables healthcare professionals to counsel their patients on injury prevention including firearm safety (90% support or strongly support);
- Advocate for federal legislation which provides an increase in funding for mental health programs (93% support or strongly support);
- Multiple COT members, through survey responses and town hall comments, emphasized violence as the "root cause" of many firearm injuries and deaths, and strongly encouraged the ACS COT to address violence prevention and intervention.

Based on our underlying philosophy and the consensus views of our surgeon members, the ACS COT is moving forward with the following:

- Approach firearm injury as a medical problem, not as a political problem;
- Encouraging the development of evidence-based violence prevention programs. We aim to implement these programs through our network of 458 ACS verified trauma centers;
- Encouraging healthcare providers to counsel patients and families on safe storage and other evidence-based prevention initiatives to decrease firearm injuries;
- Developing and advocating for a research agenda to better understand the factors that contribute to firearm injury and death to develop additional evidence-based prevention programs;
- Continuing to foster a civil, collegial discussion around how best to eliminate unnecessary injury, death, and suffering.

"*Stop the Bleed*" (http://www.bleedingcontrol.org/)—a program intended to turn bystanders into immediate responders—is critically important. The *Stop the Bleed* program is a well thought out and logically developed initiative which will save lives. Although it is not a prevention program, *Stop the Bleed* provides a framework for trauma care providers to interact with communities, and engage the public in the larger discussion that injury-related deaths can be prevented. We emphasize, *Stop the Bleed* is an integrated component to the ACS COT strategy aimed at achieving zero preventable deaths and disability through a combination of prevention and optimal care for the injured patient (http://www.nationalacademies.org/hmd/Reports/2016/A-National-Trauma-Care-System-Integrating-Military-and-Civilian-Trauma-Systems.aspx).

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